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10/037,874	11/09/2001	John C.K. Hui	4857-00001/CPG	6093

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EXAMINER

THANH, QUANG D

ART UNIT PAPER NUMBER

3764

DATE MAILED: 08/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	10/037,874	
Examiner	HUI, JOHN C.K	
Quang D. Thanh	Art Unit 3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 29 May 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-36 is/are rejected.

7) Claim(s) 18,21-26 and 31 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 20 March 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 50 6) Other:

DETAILED ACTION

Election/Restrictions

1. The restriction requirement has been withdraw in view of applicant's amendment to claim 10 as intended to positively include the external counterpulsation device with a plurality of inflatable devices, a compressed fluid source and a fluid distribution assembly as parts of the claimed combination of elements consistent with the rest of the claim.

Claim Objections

2. Claims 21-26 ~~X~~ objected to because the limitations " The computer-implemented system" recited in these claims lack antecedent basis.

3. Claim 18 is objected to because the limitations " inflatable device" and "fluid distribution assembly" have been already recited in claim 10.

4. Claim 31 is objected to because the limitation in line 3 "a leading edge... corresponding to the initiation of deflation" should be – inflation –.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 19, 21-30, and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Shabty et al. (6,450,981 B1).

7. Re claims 19 and 27, Shabty discloses a counterpulsation system (fig. 1) comprising: a counterpulsation device having a plurality of inflatable devices 22/24/26 and inflation/deflation valve 18 (fig. 1); a data structure 126 for storing treatment patient information for one or more patients (col. 2, lines 26-30 and col. 9, lines 44-48); a computer 10 connected to the counterpulsation device for controlling the operation of the counterpulsation device through each inflation/deflation cycle (col. 9, lines 58-62), for receiving the treatment information (col. 9, lines 6-62), and outputting the operation information; and an output device (display screen) connected to the computer for displaying treatment and operation information (col. 6, lines 11-20) .

8. Re claims 21-26, Shabty further discloses that the data structure is for storing demographic information including patient ID, name and medical data and for storing treatment information including ECG (EKG), blood pressure, heart rate (col. 6, line 60 to col. 7, line 45), and inflation/deflation timing data (col. 7, lines 33-37); the computer 10 communicates the patient information over a communication link to a second computing device 20 (fig. 1, col. 9, lines 19-26).

9. Re claims 27-30 and 36, Shabty further discloses that the data structure is for storing demographic information including patient ID, name and medical data and for

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storing treatment information including ECG (EKG), plethysmographic wave, blood pressure, heart rate (col. 6, line 60 to col. 7, line 45), and inflation/deflation timing data (col. 7, lines 33-37).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-10,11-17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zheng et al. (5,997,540) in view of Shabty et al. (6,450,981 B1).

12. Re claims 1, 10, and 20, Zheng et al. discloses a counterpulsation system (fig. 1) comprising: a counterpulsation device having a plurality of inflatable devices 25, a source of compressed fluid 20, a fluid distribution assembly 21/22/24 (fig. 1); a computer 7 in communication with the fluid distribution assembly of the counterpulsation device for controlling the operation of the counterpulsation device (col. 11, lines 7-19), except for a data structure for receiving/storing treatment patient information. However, Shabty teaches a counterpulsation system (fig. 1) comprising: a counterpulsation device having a plurality of inflatable devices 22/24/26 and inflation/deflation valve 18 (fig. 1); a data structure 126 for storing treatment patient information for one or more patients (col. 2, lines 26-30 and col. 9, lines 44-48); a computer 10 connected to the counterpulsation device for controlling the operation of the counterpulsation device through each

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inflation/deflation cycle (col. 9, lines 58-62) and for receiving the treatment information (col. 9, lines 6-62). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify Zheng's system, as suggested and taught by Shabty et al., to have the computer included a data structure 126 to store treatment patient information for one or more patients, for the purpose of providing and updating a patient profile database that can be used to determine the effectiveness of a counterpulsation therapy regime for an individual patient or selected study groups (col. 10, lines 1-4).

13. Re claims 2-9 and 11-17, Shabty further discloses that the data structure is for storing demographic information including patient ID, name and medical data and for storing treatment information including ECG (EKG), blood pressure, heart rate (col. 6, line 60 to col. 7, line 45); the computer 10 communicates the patient information over a communication link to a second computing device 20 (fig. 1, col. 9, lines 19-26); and Zheng further teaches that the computer controls the inflation and deflation of the inflatable devices (col. 11, lines 7-19).

14. Claims 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shabty et al. in view of Zheng et al. and Dillon (5,514,079).

15. Shagty discloses a counterpulsation system having all the claimed features except that it does not explicitly reveal timing bar having leading edge corresponding to the initiation of inflation and trailing edge corresponding to the initiation of deflation, trigger signal, timing marker with high frequency noise superimposed on an ECG in

relation to QRS wave. However, Shagty teaches that the counterpulsation therapy is carried out by timing the inflation and deflation of the treatment cuffs with certain characteristics of the patient's EKG signal and the plethysmographic blood pressure wave (col. 7, lines 33-36), and those skilled in the medical therapy art will be able to determine the timing of the inflation and deflation of the treatment cuffs and the coordination of that with the patient's natural blood flow in order to provide the desired therapy effect (col. 8, lines 56-60). Additionally, Zheng discloses a counterpulsation system having a computer that displays the wave form, detects the QRS wave of the ECG, performs adaptive processing of the impedance blood flow signals, measures the waveform's characteristic points and controls the inflation and deflation time of the counterpulsation apparatus (col. 11, lines 11-19). Moreover, Dillon teaches that, in order to regulate the timing of compression and decompression such that compression and decompression of a patient's leg is phased to the patient's heart beat, one would need EKG sensing device for monitoring the patient's heartbeat, a computer and a timer (col. 6, lines 12-19). Compression and decompression of the patient's leg is regulated by sensing the QRS complex in the heart cycle, computing an average time period between a selected number of successive QRS complexes, and initiating a timing cycle for the therapy (col. 4, lines 30-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the system in the Shabty's reference, as suggested and taught by Zheng and Dillon, to include means for measuring inflation and deflation time of the counterpulsation apparatus including timing bar having leading edge corresponding to the initiation of inflation and trailing edge

corresponding to the initiation of deflation, trigger signal, timing marker with high frequency noise superimposed on an ECG in relation to QRS wave, for the purpose of determining the timing of the inflation and deflation of the treatment cuffs and regulating the timing of compression and decompression such that compression and decompression of a patient's extremity is in coordination of that with the patient's natural blood flow in order to provide the desired therapy effect (Shabty, col. 8, lines 56-60).

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,7,9,11-13 of U.S. Patent No. 6,589,267 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of the present application are broader and are met by the narrower patent claims (i.e. the patent claim 7 contains all the limitations of the present application claim 1).

18. Re claims 1, 10 and 19, U.S. Patent No. 6,589,267 B1 (claims 1 and 7) discloses a counterpulsation system comprising: a counterpulsation device having a plurality of inflatable devices (balloon), a source of compressed fluid, a fluid distribution assembly; a data structure for storing treatment patient information, a computing device connected to the counterpulsation device for controlling the operation of the counterpulsation device and for receiving treatment patient information.
19. Re claims 2-3, 5-6, 11-13, 20-22, see claim 7 of U.S. Patent No. 6,589,267 B1.
20. Re claims 4, 14, and 23, see claim 9 of U.S. Patent No. 6,589,267 B1.
21. Re claims 7, 16, 25, see claim 11 of U.S. Patent No. 6,589,267 B1.
22. Re claims 8, 15,17,24, and 26, see claim 12 of U.S. Patent No. 6,589,267 B1.
23. Re claims 9 and 18, see claim 13 of U.S. Patent No. 6,589,267 B1.

24. Claims 27-30 and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 6,589,267 B1 in view of Shabty et al.
25. Re claims 27-28, U.S. Patent No. 6,589,267 B1 (claims 1 and 7) discloses a counterpulsation system having all the features except for an output device connected to the computer for displaying treatment and operation information. However, Shabty discloses a counterpulsation system (fig. 1) comprising: a counterpulsation device having a plurality of inflatable devices 22/24/26 and inflation/deflation valve 18 (fig. 1); a data structure 126 for storing treatment patient information for one or more patients (col.

2, lines 26-30 and col. 9, lines 44-48); a computer 10 connected to the counterpulsation device for controlling the operation of the counterpulsation device through each inflation/deflation cycle (col. 9, lines 58-62), for receiving the treatment information (col. 9, lines 6-62), and outputting the operation information; and an output device (display touch screen) connected to the computer for displaying treatment and operation information (col. 6, lines 11-20) . Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the system in U.S. Patent No. 6,589,267 B1, as suggested and taught by Shabty, to include a display touch screen connected to the computer for displaying treatment and operation information, for the purpose of allowing interaction between the operator and the computer by contacting with specific portions of the screen as prompts may indicate to set up the initiation process of the therapy (col. 6, lines 14-21).

26. Re claims 29-30, and 36, see claim 11 of U.S. Patent No. 6,589,267 B1.

27. Claims 31-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 6,589,267 B1/ Shabty et al. and further in view of Zheng et al. and Dillon (5,514,079).

28. U.S. Patent No. 6,589,267 B1/Shabty discloses a counterpulsation system having all the claimed features except that it does not explicitly reveal timing bar having leading edge corresponding to the initiation of inflation and trailing edge corresponding to the initiation of deflation, trigger signal, timing marker with high frequency noise superimposed on an ECG in relation to QRS wave. However, Shagty teaches that the

counterpulsation therapy is carried out by timing the inflation and deflation of the treatment cuffs with certain characteristics of the patient's EKG signal and the plethysmographic blood pressure wave (col. 7, lines 33-36), and those skilled in the medical therapy art will be able to determine the timing of the inflation and deflation of the treatment cuffs and the coordination of that with the patient's natural blood flow in order to provide the desired therapy effect (col. 8, lines 56-60). Additionally, Zheng discloses a counterpulsation system having a computer that displays the wave form, detects the QRS wave of the ECG, performs adaptive processing of the impedance blood flow signals, measures the waveform's characteristic points and controls the inflation and deflation time of the counterpulsation apparatus (col. 11, lines 11-19). Moreover, Dillon teaches that, in order to regulate the timing of compression and decompression such that compression and decompression of a patient's leg is phased to the patient's heart beat, one would need EKG sensing device for monitoring the patient's heartbeat, a computer and a timer (col. 6, lines 12-19). Compression and decompression of the patient's leg is regulated by sensing the QRS complex in the heart cycle, computing an average time period between a selected number of successive QRS complexes, and initiating a timing cycle for the therapy (col. 4, lines 30-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the system in the U.S. Patent No. 6,589,267 B1/ Shabty's reference, as suggested and taught by Zheng and Dillon, to include means for measuring inflation and deflation time of the counterpulsation apparatus including timing bar having leading edge corresponding to the initiation of inflation and trailing edge

corresponding to the initiation of deflation, trigger signal, timing marker with high frequency noise superimposed on an ECG in relation to QRS wave, for the purpose of determining the timing of the inflation and deflation of the treatment cuffs and regulating the timing of compression and decompression such that compression and decompression of a patient's extremity is in coordination of that with the patient's natural blood flow in order to provide the desired therapy effect (Shabty, col. 8, lines 56-60).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang D. Thanh whose telephone number is (703) 605-4354. The examiner can normally be reached on Monday-Thursday & alternate Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (703) 308-2698. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1148.

Quang D. Thanh
Patent Examiner
Art Unit 3764
July 25, 2003

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QT


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